

BK030062

Section 8- 510(k) Summary of Safety and Effectiveness

8.1
Statement This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

8.2
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8.3
Company
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8.4
Device
Name **Proprietary Name:** Haemonetics® Model 215 Automated Glycerolization /
Deglycerolization System
Common Name: ACP 215
Classification Name: Processing System for Frozen Blood

8.5
Predicate
Legally
Marketed
Devices The Haemonetics ACP 215, which is the subject of this submission, is substantially equivalent to the previously cleared ACP 215 cleared via BK000002 on May 4, 2001 by Haemonetics Corporation.

8.6

Device

Description

The ACP 215 is an automated cell processing system intended to be used glycerolize and red blood cells.

8.7

Device

**Indications
and Intended
use**

Indications for use:

The ACP 215 is intended to glycerolize and deglycerolize red blood cells derived from whole blood that have been stored in any approved anticoagulant/additive solution for 6 days at 1-6°C prior to glycerolization. Red blood cells that have been collected and stored in CPDA-1, CPD/AS-1, or CP2D/AS-3, glycerolized using the ACP 215, frozen at -65 °C or colder, deglycerolized by the ACP 215, and stored in Haemonetics AS-3 at 1-6° may be labeled for extended storage for 14 days.

Red blood cells collected in any other anticoagulant / additive solution will be labeled with a 24-hour outdate.

The following page contains a table comparing the new versus the predicate device.



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8.1 TABLE OF SUSTANTIAL EQUIVALENCE

Characteristics	Predicate Device ACP 215 System	Proposed Device ACP 215 System
Protocol	Automated Glycerolization/ Deglycerolization	Automated Glycerolization/ Deglycerolization
Hardware	ACP 215	ACP 215
Disposable	LN 225-00 and LN235-00	LN 225-00 and LN235-00 (or LN236-00)
Washing Solution	12 %NaCl 0.9% NaCl/ 0.2gm Glucose	12 %NaCl 0.9% NaCl/ 0.2gm Glucose
Intended Use	The ACP 215 is intended to Glycerolize and Deglycerolize Red blood Cells up to 6 days old. Cells collected and stored in CPDA-1 may be labeled for extended storage up to 14 days. Cell collected in other solutions may be stored for 24 hours post-deglycerolization.	The ACP 215 is intended to glycerolize and deglycerolize red blood cells derived from whole blood that have been stored in any approved anticoagulant/additive solution for 6 days at 1-6°C prior to glycerolization. Red blood cells that have been collected and stored in CPDA-1, CPD/AS-1, or CP2D/AS-3, glycerolized using the ACP 215, and frozen at -65 °C or colder, deglycerolized by the ACP 215, and stored in Haemonetics AS-3 at 1-6° may be labeled for extended storage for 14 days. Red blood cells collected in any other anticoagulant / additive solution will be labeled with a 24-hour outdate.
Product Quality	<u>Recovery:</u> 95% confidence that 90% units met the 80% minimum recovery <u>Hemolysis:</u> 95% confident that at 90% of the units met the maximum hemolysis of 1%	<u>Recovery:</u> 95% confidence that 90% units met the 80% minimum recovery <u>Hemolysis:</u> 95% confident that at 95% of the units met the maximum hemolysis of 1%
Post-Washing Storage	14-days post deglycerolization storage.	14-days post deglycerolization storage

Applicant



Date

9/23/03